

Translation

PATENT COOPERATION TREATY

PCT/JP2003/016978



PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P03-0131PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/016978	International filing date (day/month/year) 26 December 2003 (26.12.2003)	Priority date (day/month/year) 26 December 2002 (26.12.2002)
International Patent Classification (IPC) or national classification and IPC C07K 14/47, A61K 38/00, A61P 1/18, 3/04, 3/06, 3/10, 7/02, 9/10, 13/00, 15/00, 15/06, 15/08, 25/28, 35/00, 35/04, 43/00		
Applicant TAKEDA CHEMICAL INDUSTRIES, LTD.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 9 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☐ (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☒ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) 1 disc, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☒ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

Date of submission of the demand 06 April 2004 (06.04.2004)	Date of completion of this report 13 September 2004 (13.09.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

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Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description: _____, as originally filed/furnished

pages _____

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims: _____, as originally filed/furnished

pages _____

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings: _____, as originally filed/furnished

pages _____

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Supplemental Box Relating to Sequence Listing

Continuation of Box No. 1, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis that of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purpose of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

* If item 4 in Box No. 1 applies, the listing and /or table(s) related thereto, which form part of the basis of the report, may be marked "superseded".

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1, 3-47

because:

☒ the said international application, or the said claims Nos. 16-26, 42-44
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1, 3-15, 27-37
are so unclear that no meaningful opinion could be formed (*specify*):

See supplemental sheet

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1, 3-47

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the
Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with
the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ see Supplemental Box for further details.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Claims 16-26 and 42-44

The inventions that are set forth in claims 16-26 and 42-44 pertain to "methods for the treatment of the human body by surgery or therapy, and to diagnostic methods," and thus relate to a subject matter for which this International Preliminary Examining Authority is not required to carry out an international preliminary examination.

Claims 1, 3-15 and 27-37

The description only sets forth a number of specific examples of the metastatin derivatives which are represented by the broad structural formula that is set forth in claim 1.

Consequently, claim 1 is not fully supported by the description, and, even with consideration of common technical knowledge at the time the present application was filed, is not satisfactorily set forth therein.

Therefore, it is impossible to conduct a meaningful search in relation to the invention that is set forth in claim 1.

The same is true in relation to claims 3-15 and 27-37, which cite claim 1.

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
 - ☒ not complied with for the following reasons:

See supplemental sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 2

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: IV.3

Independent claim 2 pertains to metastatin derivatives which are represented by the chemical formula that is set forth in the present application.

On the other hand, the feature that is common to independent claims 38-41 and 45-47 is the feature of being related to an agonist against the metastatin receptor.

However, as a result of a search, it has become apparent that said metastatin receptor agonist is disclosed in the document (Matthew D. RINGEL et al., "Metastin Receptor is Overexpressed in Papillary Thyroid Cancer and Activates MAP Kinase in Thyroid Cancer Cells," J. Clin. Endocrinol. Metab., Vol. 87, No. 5, May 2002, pp. 2399-2402); therefore, the metastatin receptor agonist in question is not novel.

As a result, said metastatin receptor agonist does not define a contribution over the prior art, and hence this common feature is not special technical feature in the meaning of PCT Rule 13.2, second sentence.

Therefore, there is no feature that is common to independent claims 38-41 and 45-47.

In addition, there is no other common feature which can be considered to be special technical feature in the meaning of PCT Rule 13.2, second sentence, among independent claims 2, 38-41 and 45-47; therefore, it is impossible to find that these different inventions have a technical relationship in the meaning of PCT Rule 13.

Consequently, it is apparent that independent claims 2, 38-41 and 45-47 do not fulfill the requirement of unity of invention.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2	YES
	Claims		NO
Inventive step (IS)	Claims	2	YES
	Claims		NO
Industrial applicability (IA)	Claims	2	YES
	Claims		NO

2. Citations and explanations

- Document 1: WO 02/092829 A1 (Takeda Chemical Industries, Ltd.), 21 November 2002
- Document 2: WO 01/75104 A1 (Takeda Chemical Industries, Ltd.), 11 October 2001
- Document 3: WO 00/24890 A1 (Takeda Chemical Industries, Ltd.), 04 May 2000
- Document 4: Matthew D. RINGEL et al., "Metastin Receptor is Overexpressed in Papillary Thyroid Cancer and Activates MAP Kinase in Thyroid Cancer Cells," J. Clin. Endocrinol. Metab., Vol. 87, No. 5, May 2002, pages 2399 to 2402
- Document 5: Masato KOTANI et al., "The Metastasis Suppressor Gene KiSS-1 Encodes Kisspeptins, the Natural Ligands of the Orphan G Protein-coupled Receptor GPR54," J. Biol. Chem., Vol. 276, No. 37, 2001, pages 34631 to 34636
- Document 6: Sang-Kyou HAN et al., "Orphan G Protein-coupled Receptors MrgA1 and MrgC11 are distinctively activated by RF-amide-related peptides through the $G\alpha_{q/11}$ pathway," Proc. Natl. Acad. Sci. USA, Vol. 99, No. 23, November 2002, pages 14740 to 14745

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The invention that is set forth in claim 2 involves an inventive step in relation to documents 1-6 cited in the international search report.

The metastatin derivatives (I) which are represented by the structural formula that is set forth in claim 2 are not disclosed in any of the related documents, and are not obvious to a person skilled in the art.